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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,354	06/27/2003	Stanley T. Crook	MSIBIS-0002USC2	2899
27180 7590 07/03/2007 ISIS PHARMACEUTICALS INC 1896 RUTHERFORD RD. CARLSBAD, CA 92008			EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,354	Applicant(s) CROOK ET AL.	
	Examiner Frank W. Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38,39,41-43,45-47,95,97-99,101,103-105 and 107-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38,39,41-43,45-47,95,97-99,101,103-105 and 107-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on April 17, 2007 has been entered and the terminal disclaimers filed on April 17, 2007 have been accepted by the office. The claims pending in this application are claims 36, 38, 39, 41-43, 45-47, 95, 97-99, 101, 103-105, and 107-111. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response and the terminal disclaimers filed on April 17, 2007.

Information Disclosure Statement

2. Some references in the information disclosure statement filed on January 18, 2005 (see sheets 11 and 12) are books. Since applicant did not submit these books in cases in 09/884,317, 09/260,310, 09/076,206, and this instant applicant, these references have not been considered. Note that applicant does not address this issue in the response filed on April 17, 2007.

Specification

3. The disclosure is objected to because of the following informalities: (1) the amendments related to lines 4-6 of page 1 of the specification (see page 2 of applicant's remarks) should be corrected because applicant has replaced lines 4-6 of page 1 of the specification without showing all the changes relative to the previous version of the paragraph. see 37 CFR 1.121 for detail; (2) it is unclear that the word "which" in the phrase "the entirety of which is incorporated herein by reference" in the amendments related to lines 4-6 of page 1 of the specification (see page 2 of applicant's remarks) means U.S. Patent Application Serial No. 09/076,206 or U.S. Provisional

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Application Serial. No. 60/076,534 or means something else; and (3) there are several nucleotide sequences with more than 10 nucleotides in Figures 1, 4, 5, 7-12, 24, and 27. However, there are no SEQ ID Nos for these nucleotide sequences in Figures 1, 4, 5, 7-12, 24, and 27 and there is no description for these nucleotide sequences and there are no SEQ ID Nos for these nucleotide sequences in BRIEF DESCRIPTION OF THE DRAWINGS of the specification. Note that applicant does not address item (3) in the response filed on April 17, 2007.

Appropriate correction is required.

Sequencing Listing

4. The paper copy of new sequencing listing filed on April 17, 2007 has been obtained. However, in an unknown reason, the computer readable form of the sequencing listing has not been entered to database by the office. If applicant has not submitted the computer readable form of the sequencing listing in the response to the previous office, please resubmit a computer readable form of the sequencing listing.

Claim Objections

5. Claim 36 is objected to because of the following informality: "combining with said complex under competitive binding conditions the mixture of compounds" in step (b) should be "combining said complex with the mixture of compounds under competitive binding conditions".
6. Claim 38 or 45 or 101 is objected to because of the following informality: "said nucleic acid" should be "said nucleic acid target".

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7. Claim 41 is objected to because of the following informality: "combining with a further portion of said complex under competitive binding conditions the mixture of compounds" in step (b) should be "combining a further portion of said complex with the mixture of compounds under competitive binding conditions".

8. Claim 42 is objected to because of the following informality: "combining with said first complex a combinatorial mixture of compounds" in step (b) should be "combining said first complex with a combinatorial mixture of compounds".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 36, 38, 39, 41-43, 45-47, 95, 97-99, 101, 103-105, and 107-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 36 or 41 is rejected as vague and indefinite. Although the claim is directed to a method for identifying a compound, there is no method step for identifying a compound and the goal (see the preamble of the claim) cannot be reached. Furthermore, from the claim, it is unclear that, in which situation, a compound can be identified. Please clarify.

12. Claim 36 is rejected as vague and indefinite. Since step (d) does not indicate to form fragments, it is unclear how to collect mass spectral data for the fragmentation in step (e). Please clarify.

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13. Claim 36 recites the limitation in “the existence and degree of competitive binding” in step (f). There is insufficient antecedent basis for this limitation in the claim because there is no phrase “existence and degree of competitive binding” in steps (a) to (d). Please clarify.

14. Claim 39 is rejected as vague and indefinite. Since RNA is ribonucleic acid, it is unclear how said RNA includes one or more deoxynucleotides as recited in claim 39. Please clarify.

15. Claim 41 is rejected as vague and indefinite. Since step (a) does not indicate to form fragments, it is unclear how to acquire fragmentation data from the mass spectrometric analysis of the complex as recited in step (b). Please clarify.

16. Claim 41 is rejected as vague and indefinite. Since step (e) does not indicate to form fragments, it is unclear how to collect mass spectral data for the fragmentation in step (f). Please clarify.

17. Claim 41 recites the limitation in “the existence and degree of competitive binding” in step (g). There is insufficient antecedent basis for this limitation in the claim because there is no phrase “existence and degree of competitive binding” in steps (a) to (f). Please clarify.

18. Claim 42 is rejected as vague and indefinite. Although the claim is directed to a method for identifying a combinatorial mixture compound, there is no method step for identifying a combinatorial mixture compound and the goal (see the preamble of the claim) cannot be reached. Furthermore, from the claim, it is unclear that, in which situation, a compound can be identified. Please clarify.

19. Claim 42 recites the limitation “the ion abundance” in step (a) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “ion abundance” in the preamble of the claim. Please clarify.

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20. Claim 42 recites the limitation “the ion abundance of said first complex” in step (e) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “ion abundance of said first complex” in steps (a) to (d) of the claim. Please clarify.

21. Claim 42 is rejected as vague and indefinite in view of step (e) of the claim. Since said combination in step (d) is a complex formed by said first complex and a combinatorial mixture of compounds and is not said first complex alone, it is unclear how to collect mass spectral data on the ion abundance of said first complex from step (d). Please clarify.

22. Claim 42 recites the limitation “said determination” in step (e) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word “determination” before “said determination”. Please clarify.

23. Regarding claim 43, the phrase “preferentially” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Please clarify.

24. Claim 43 recites the limitation “the combinatorial mixture which preferentially bind with said bimolecular target” in step (e) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “combinatorial mixture which preferentially bind with said bimolecular target” in claim 42. Please clarify.

25. Claim 42 is rejected as vague and indefinite because it is unclear that the phrase “said RNA corresponds to a 16S rRNA A-site” means that said RNA comprises a 16S rRNA A-site or said RNA is a 16S rRNA A-site. Please clarify.

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26. Claim 47 is rejected as vague and indefinite. Since RNA is ribonucleic acid, it is unclear how said RNA includes one or more deoxynucleotide subunits as recited in claim 47. Please clarify.

27. Claim 95 or 97 is rejected as vague and indefinite because it is unclear that said compound is a standard binding compound in step a) or any kind of compound of the mixture of compounds or a compound which binds to a nucleic acid target in the preamble of claim 36. Please clarify.

28. Claim 99 or 104 is rejected as vague and indefinite because it is unclear that said compound is a standard binding compound in step a) or any kind of compound of the mixture of compounds or a compound which binds to a nucleic acid target in the preamble of claim 41. Please clarify.

29. Claim 105 or 108 is rejected as vague and indefinite because it is unclear that said compound is a standard binding compound in step a) or any kind of compound of the mixture of compounds or a compound which binds to a nucleic acid target in the preamble of claim 42. Please clarify.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. No claim is allowed.


32. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

June 22, 2007


FRANK LU
PRIMARY EXAMINER